



Fig. 6 – Inadvertent inoculation of lower eyelid [Fenner F, Henderson, DA, et al. Smallpox and its Eradication. WHO. 1988, Reprinted with permission of WHO]

- G. *Generalized vaccinia* – This complication is characterized by a vesicular rash of varying extent resulting from blood-borne dissemination of vaccinia virus (Fig. 7). It is most frequently seen following primary vaccination and occurs at a rate of about 1 in 5000 vaccinations. Lesions occur between 6-9 days following vaccination and can be few or generalized. The rash of is generally self-limited in persons with no underlying illnesses (immune deficiencies) and usually requires no treatment with VIG except in patients who appear toxic or who have serious underlying conditions.



Fig. 7 - Generalized vaccinia, 10 days after vaccination, benign course, no scarring. [Fenner F, Henderson, DA, et al. Smallpox and its Eradication. WHO. 1988, Reprinted with permission of WHO]

- H. *Eczema vaccinatum* – This complication is seen in vaccine recipients who have active or healed eczema or other chronic skin conditions. It can also occur in persons with these conditions who come into contact with a recently vaccinated

individual. Vaccinial skin lesions can progress to cover all or most of the area(s) that are or were affected by the eczema or chronic skin condition (Fig. 8). Fever and generalized lymphadenopathy may also occur. The illness is usually mild and self-limited, but can be severe and occasionally fatal. The most serious cases appear to occur in primary vaccinees and close contacts with eczema of vaccinees, and are independent of the activity of underlying eczema. Previous studies have indicated that this complication occurs at a rate of about 1 in 26,000 primary vaccinations. VIG is effective in treating serious cases of eczema vaccinatum.



Fig. 8 – Eczema vaccinatum in an unvaccinated child resulting from contact with a recently vaccinated sibling. . [Fenner F, Henderson, DA, et al. Smallpox and its eradication. WHO. 1988, Reprinted with permission of WHO]

- I. *Progressive vaccinia* (vaccinia necrosum or gangrenosa) – This severe and potentially fatal complication occurs in persons with underlying immune deficiencies and can occur following primary or re-vaccination. It is characterized by failure of the vaccine site lesion to heal, with progressive necrosis of the vaccination site and surrounding areas (Fig. 9). Secondary lesions may appear at other sites of the body and also exhibit progressive necrosis. VIG has been used to treat this complication with varying success.



Fig. 9 – Progressive vaccinia, that was fatal, in a child with an immunodeficiency. [Fenner F, Henderson, DA, et al. Smallpox and its eradication. WHO. 1988, Reprinted with permission of WHO]

- J. *Post-vaccination encephalitis* – Encephalitis, characterized by fever, headache, vomiting, drowsiness, and occasional spastic paralysis, meningeal signs, convulsions, or coma, occurred between 8-15 days post-vaccination at a rate of 1 case per 300,000 vaccinations. The majority of cases occurred in primary vaccinees <1 year of age. The incidence of post-vaccination encephalitis in primary vaccinees also increased with increasing age. There are no other known predisposing factors for this complication. Approximately 15-25% of cases with post-vaccination encephalitis died and an additional 25% had permanent neurological sequelae. There is currently no known treatment for post-vaccination encephalitis and VIG is not effective or indicated for this complication.

1. Indications and Guidelines for Vaccinia Immune Globulin (VIG) Administration

The recommended dosage of VIG for treatment of complications due to vaccinia vaccination is 0.6 mL/kg of body weight. VIG must be administered intramuscularly (IM) and should be administered as early as possible after the onset of symptoms. Because the therapeutic dose of VIG may be large (e.g., 42mL for a 70 kg person), the product should be given in divided doses over a 24 - 36 hour period. Doses may be repeated at 2-3 day intervals until no new lesions appear.

Post-vaccination complications for which VIG may be indicated include:

1. Eczema vaccinatum
2. Progressive vaccinia (vaccinia necrosum)
3. Severe generalized vaccinia if the patient has a toxic condition or serious underlying illness.
4. Inadvertent inoculation of the eye or eyelid without vaccinia keratitis

***VIG is not indicated for the treatment of post-vaccination encephalitis and is contraindicated for vaccinia keratitis.**

The currently limited supplies of VIG do not allow for its concomitant administration with vaccine for the prevention of potential complications. VIG use should be reserved for treatment of the most serious or life-threatening complications.

2. CDC Recommendations for Handling, Cleaning and Sterilizing Bifurcated Immunization Needles in Healthcare Settings

Background

Sterile, bifurcated needles are used to administer smallpox immunization. The needles are designed to hold the designated dose of vaccine (2.5 µl) between the needle prongs to

allow delivery to the skin surface. Once on the skin, the needle is used to make 15 superficial punctures at the vaccination site to permit percutaneous penetration of the vaccine. Trace amounts of blood at the vaccination site are evidence of successful vaccine delivery.

Bifurcated needles may arrive from the manufacturer sterilized and individually wrapped, or in bulk, requiring subsequent sterilization prior to use. These needles are intended for single-patient use followed by disposal in a puncture-resistant sharps container. Because of limited supplies, especially during mass vaccination programs, it may be necessary to reprocess and reuse these needles.

The strategies and procedures described here are restricted to the cleaning and reprocessing of bifurcated needles ONLY.

Protocols for reprocessing bifurcated needles must address: 1) the prevention of blood exposures and patient-to-patient transmission of bloodborne viruses (i.e., hepatitis B and C viruses [HBV, HCV], and human immunodeficiency virus [HIV]); and 2) prevention of sharps injury and occupational transmission of bloodborne viruses to healthcare personnel. The following procedures are designed to protect both patients and healthcare personnel involved in smallpox vaccination programs.

1. **Initial Sterilization of Unsterile Bifurcated Needles Received From the Manufacturer in Bulk Supply.** Needles received in bulk from the manufacturer should be assumed to be clean and ready for packaging and sterilization. If there is any concern regarding the cleanliness of these items, they should be cleaned then sterilized as described below.
2. **Identify Resources.** Identify equipment and personnel to carry out reprocessing. The reprocessing area should either have an ultrasonic bath, commercial dishwasher, and an autoclave or dry heat sterilizer. The area should be of sufficient size to have clearly demarcated dirty and clean areas. The flow of traffic should always be from dirty to clean.
3. **Methods for Reprocessing Bifurcated Needle.** Moist heat sterilization (i.e., autoclaving) or dry heat sterilization are the preferred methods for sterilizing cleaned bifurcated needles. However, boiling or flaming, as described below, may be used if an autoclave or a forced air dry heat oven is not available. These alternative methods have some historical precedence, especially in developing nations, but have not been validated.
 - A. Care in handling. To prevent worker injury, used needles should be handled as little as possible during reprocessing. The use of fine mesh containers with secure tops that facilitate containment and transfer during reprocessing is preferred. Tongs, forceps, hemostats, or other devices that

eliminate the need for hands-on contact with needles should be used to transfer them from their container.

- B. Cleaning. Used needles MUST BE CLEANED prior to sterilization. Place needles in a soaking solution immediately after use and prior to any physical cleaning. Soaking will facilitate cleaning by preventing blood and organic soil from drying on the needle. Commercial products used by healthcare facilities for soaking contaminated instruments (e.g., any detergent, detergent-disinfectant, enzyme formulation/cleaner) are appropriate for this purpose. Do not use alcohol, glutaraldehyde, or formaldehyde as a soaking solution for the needles (these will fix protein to the needle surfaces). Also avoid use of strong oxidizing solutions (hypochlorites, peroxides, peracetic acid) because these may damage the needle tip.

Transport used needles in the soaking solution (cover or cap the container) and send to designated area for cleaning and reprocessing.

Automated cleaning with an ultrasonic cleaning device or commercial dish/glassware washer is preferred to manual cleaning as there is less opportunity for worker injury. The manufacturer's instructions for use of the device should be followed. The needles should then be rinsed with potable water, and allowed to air dry on a clean surface. Personnel should wear gloves during the cleaning process and use transfer devices (e.g., tongs, forceps, hemostats) as needed to avoid direct handling of needles.

- C. Autoclaving. Bifurcated needles that have been cleaned and dried are ready to be packaged and autoclaved. Needles may be individually wrapped or placed in groups of 10-15 in plastic/paper peel-down packages or pouches, or clean screw-top glass container, and autoclaved. The bifurcated end of the needle should point toward the bottom of the tube/pouch away from the opening to allow easy aseptic retrieval. The manufacturer's instructions for use of the autoclave should be followed. Sterilization times will vary depending on temperature and load (i.e., 121 °C for 30 minutes or 133 °C for 4 minutes). The tubes/packs should be placed in a rack or carrier that holds the tubes in a horizontal or slightly slanted position to ensure that the steam will penetrate fully to the bottom. During autoclaving, tops of glass tubes should be loose enough to allow penetration of steam and prevent breakage of the container. After autoclaving and cooling, caps should be tightly screwed.
- D. Dry Heat Sterilization. Screw capped glass test tubes are the best choice for dry heat sterilization. Clean and package bifurcated needles as above for glass tubes, i.e. cap tubes but leave loose enough to allow for air. The needles can be placed in a dry heat oven and baked as follows: (i) 170°C

for 60 minutes; (ii) 160°C for 120 minutes; (iii) 150°C for 150 minutes; (iv) 140°C for 180 minutes; or (v) 121°C for overnight.

4. **Other Sterilization Alternatives.** Boiling and flaming are alternative methods for sterilizing bifurcated needles, but should be used only when other options are not available.

A. Boiling. After cleaning, needles that will be reused may be placed in boiling water for 20 minutes, allowed to air dry, and then stored in a sterile receptacle. To minimize handling before and after sterilization heat-resistant fine mesh containers should be used where possible. If such containers are not available, a transfer device (e.g., tongs, forceps, hemostat) should be used to insert and remove needles from the water bath. The transfer device should be boiled along with the needles to facilitate aseptic removal. Although the handle of the transfer device need not be immersed in the boiling water, it will become very hot during needle reprocessing. Care should be taken to prevent burn injury during handling. Needles must be thoroughly dried to ensure that no residual water enters the vaccine vial. This is best accomplished by placing the needles on one half of an absorbent, plastic-backed, sterile barrier and folding the other half over the needles, providing a protective cover. When dry, the needles should be transferred aseptically into a dry sterile container (e.g., glass tube) with the bifurcated ends pointed away from the opening to permit aseptic retrieval. The top of the receptacle should be secured tightly to prevent contamination.

B. Flaming. In the past, flaming has been used to reprocess bifurcated needles, but no data exists on sterilization efficacy. Flaming should be used only when the needle must be reused immediately (i.e., a mass vaccination campaign is underway, vaccine recipients are present, and a supply of new or reprocessed sterile needles is not available) and only when none of the other sterilization methods described above are available. Pass the bifurcated end of the needle through the flame of an alcohol lamp or Bunsen burner. If an alcohol burner is used, the concentration of the alcohol must be 95% for adequate burn. The optimal duration of exposure to the flame is not known. The needle must become sufficiently hot to allow sterilization. However, to maintain needle integrity, the needle should not remain in the flame for more than 3 seconds. Measures should be taken to prevent burn injury to the fingers by handling the blunt end of the needle with a non-conductive device (i.e., forceps or tweezers with rubber or hard plastic handles). Allow the needle to cool completely before inserting into the vaccine.

Flaming is not considered a terminal reprocessing procedure as it does not provide an environment for maintaining sterile conditions. If

needles that have been flamed for immediate reuse will be used again in the future, they should be cleaned and sterilized (autoclaving, baking, or boiling), as described above.

Frequency of Reuse. A bifurcated needle should not be reprocessed and reused more than 50 times. Reports have shown that vaccination effectiveness was reduced to 80.8% with needles used 86-172 times. Procedures should be established to monitor the frequency of needle reuse.

Prevention of cross-contamination. Patient-to-patient transmission of bloodborne viruses has been associated with contamination of multi-dose vials. To prevent opportunity for such transmission, a contaminated needle should never be allowed to reenter a vaccine vial. Furthermore, surfaces where vaccine is being handled should be free of visible blood, body fluids or other organic soil. Preparation of vaccine and needle reprocessing should be physically separate.

<p>If a contaminated needle is inadvertently redipped into a vaccine vial, that vial should be removed and not used for further vaccination.</p>
